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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,159	06/14/1999	SEAN A. MCCARTHY	10147-6	3785

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EXAMINER	
JIANG, DONG	
ART UNIT	PAPER NUMBER
1646	20

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/333,159	MCCARTHY ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,12 and 24-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *66* is/are allowed.

6)☒ Claim(s) *1,3-7,12,26-28,30-34 and 36-65* is/are rejected.

7)☒ Claim(s) *2,24,25,29 and 35* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment in paper No. 19, filed on 15 May 2003 is acknowledged and entered. Following the amendment, claims 1, 32, 33, 37, 39, 43, 44, 54 and 65 are amended, and the new claims 41-66 are added.

Currently claims 1-7, 12, and 24-66 are pending, and under consideration.

Withdrawal of Objections and Rejections:

The rejection of claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The prior art rejection of claims 32, 37, 39, 40, 44, 54 and 65 is withdrawn in view of applicant's amendment.

Formal Matters:

Claim 42 is objected under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim depends from claim 37, which recites "the polypeptide is a variant of the polypeptide encoded by SEQ ID NO:46 in lines 1-2, whereas claim 42 recites "the polypeptide is an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO:46. Thus, claim 42 is not further limiting claim 37 as the polypeptide cannot be *a variant* of the polypeptide encoded by SEQ ID NO:46, and meanwhile *an immunogenic portion* of the protein having the amino acid sequence encoded by SEQ ID NO:46.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 32, 37, 39, 43, 44, 54 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of the claims introduces the limitation of "over its full length". Applicants have not pointed out, nor can the Examiner locate, the basis in the specification for such a limitation.

This is a new matter rejection.

If applicants amend the claims to remove the new matter, the prior art rejection of the claims made in the last Office Action (paper No. 17) would be reinstated.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 40 and 43-65 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 remains indefinite for the limitation of "encodes a variant" in part e), for the reasons set forth in the last Office Action, paper No. 17, mailed on 14 February 2003, at page 3.

Applicants argument, filed on 15 May 2003 (paper No. 19) has been fully considered, but is not deemed persuasive for reasons below.

At pages 5-6 of the response, the applicant argues that there is no mutually exclusive (i) the preamble "encodes an immunogneic portion of the protein having the amino acid sequence encoded by SEQ ID NO:46", and (ii) the limitation "encodes a variant of the amino acid sequence encoded by SEQ ID NO:46", that the specification describes the protein variants and how to use polypeptides of the invention, and that a person of ordinary skill in the art recognizes that many variants of the TANGO294 still may retain immunogenic portions of the TANGO294. These arguments is not persuasive because they are not the issue of the rejection. The main issue

is that the preamble of the claim, as written, is interpreted as the isolated nucleic acid i) encodes *a protein consisting of* an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO:46, and with that interpretation, it cannot also encode a variant of the amino acid sequence encoded by SEQ ID NO:46. Claims 54 and 65 remain similarly indefinite. If applicants amend the claims to read on *a protein comprising of* an immunogenic portion, they would be considered for the issue of enablement under 35 U.S.C. 112, first paragraph.

The remaining claims are rejected for depending from an indefinite claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 28 and 31 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record in the previous Office Actions, paper Nos. 7, 9 and 17.

Applicants argument in paper No. 19 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues that the specification describes domains constituting regions of known activity, and the TAGO294 is known to contain a lipase serine active site, and that thus applicants have provided an example of at least one small portion of a large enzyme molecule capable of catalytic activity, and persons of ordinary skill in the art can easily determine which protein fragments and variants of the invention, regardless of their size, possess a TANGO294 activity. This argument is not persuasive because the issue is not whether TANGO294 contains a conservative functional domain such as a lipase serine active site, or it is a lipase, rather, the issue is that the present claims encompass small fragments such as 25 amino acids, which, by itself, may not be sufficient for the functional activity even though the fragment is located in the active site. The Examiner is not aware that the prior art has established that a fragment of 25 amino acids of any enzyme possesses enzymatic activity. The specification provides neither guidance nor working examples regarding such functional

fragments. Therefore, it is unpredictable such a small fragment would possess the biological property, thus undue experimentation would be required prior to using the claimed invention.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-7, 12, 26, 30, 33, 34, 36, 38, 41-43, 47, 51, 53, 56-62, and 64 remain rejected under 35 U.S.C. 102(a) as being anticipated by Blanchard et al., US 5,807,726, for the reasons set forth in the last Office Action, paper No. 17, at pages 4-5.

Applicants argument paper No. 17 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that claims 1, 32, 37, 39, 43, 44, 54 and 65 have been amended to include the language "over its full length", thereby obviating the rejection with respect to those claim and any depending therefrom. This argument is not persuasive because, while the addition of "over its full length" in the claims overcomes the prior art with respect to the hybridization variants, the amendment does not overcome the prior art with respect to the fragment of the polypeptide. As addressed in the last Office Action, Blanchard's nucleic acid molecule comprises "a fragment of SEQ ID NO:45 or 46" (as claims 1 and 43, part b), and claims 26 and 47, for example), a nucleic acid encoding "a polypeptide comprising a fragment of the amino acid sequence encoded by SEQ ID NO:46" (as claims 1 and 43, part d), and claims 30 and 51, for example), or a nucleic acid encoding "a polypeptide comprising a fragment which comprises an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO:46" (as claim 33, for example). As such, the prior art reference still anticipates these claims.

Claims 1, 3-7, 12, 26, 30, 33, 34, 36, 38, 41-43, 47, 51, 53, 56-62, and 64 also remain rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (J. Biol. Chem., 1991, 266: 22479-84), for the reasons set forth in the last Office Action, paper No. 17, at page 5. It is further noted that Anderson's nucleic acid encodes a polypeptide comprising a fragment of SEQ ID NO:47 (residues 115-125) of the present invention with 100% sequence identity.

Conclusion:

Claim 66 is allowable.

Claims 2, 24, 25, 29 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Advisory Information:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/18/03

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER